Sagimet Biosciences Reports Third Quarter 2026 Financial Results and Provides Corporate Updates

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- *Registrational U.S. AURORA Phase 3 clinical trial underway for denifanstat in moderate to severe acne, with topline data anticipated in the second half of 2027*
- *Positive denifanstat Phase 3 clinical trial results in China from license partner Ascletis, and continued improvement and sustained efficacy across all efficacy endpoints through 52 weeks in the open-label extension clinical trial, presented at EADV 2026 and Fall Clinical Dermatology 2026*
- *Completed underwritten offering of Series A Common Stock and pre-funded warrants in October, with gross proceeds of $115 million*
- *Pro forma cash and investments balance of approximately $356 million as of September 30, expected to fund current operations through mid-2029 including through readout of data from the denifanstat AURORA Phase 3 clinical trial in moderate to severe acne and potential NDA submission*

FOSTER CITY, Calif., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing inhibitors of fatty acid synthase (FASN), a key lipid synthesis regulator, for acne, today reported financial results for the quarter ended September 30, 2026, and provided corporate updates.

“Building on the positive Phase 3 results from our license partner Ascletis, we have initiated our pivotal U.S. AURORA Phase 3 clinical trial,” said David Happel, Chief Executive Officer of Sagimet. “With our October equity financing, we are well positioned to fund our programs through mid-2029, including the anticipated Phase 3 denifanstat data readout and the potential submission of an NDA. If approved, denifanstat would be the first oral acne treatment with a novel mechanism of action approved by the FDA in more than 40 years, offering a new treatment option for approximately 10 million Americans living with moderate to severe acne.”

Recent Corporate Highlights

- **AURORA Phase 3 clinical trial:** In October 2026, Sagimet announced that the first patient had been dosed in its AURORA registrational U.S. Phase 3 clinical trial of once-daily denifanstat in adults and adolescents aged 12 years and older with moderate to severe acne. The Company plans to enroll approximately 800 patients in AURORA, including approximately 450 adolescents aged 12 to 17 years. The trial is intended to support a potential U.S. New Drug Application (NDA), with topline data expected in the second half of 2027.
- **Equity financing:** In October 2026, Sagimet completed an underwritten offering of Series A common stock and pre-funded warrants, resulting in approximately $115.0 million in gross proceeds, before deducting underwriting discounts and commissions and other offering expenses.
- **TVB-3567:** The single- and multiple-ascending dose and food effect parts of the first-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 completed dosing and TVB-3567 was generally well tolerated. Part D of the trial evaluating pharmacodynamic biomarkers in acne patients is ongoing. Phase 2 doses have been identified, and the Company anticipates initiating the Phase 2 clinical trial of TVB-3567 in moderate to severe acne patients before the end of 2026.
- **KOL event:** On September 30, 2026, Sagimet hosted a virtual key opinion leader (KOL) event featuring Julie Harper, MD, Founding Director and past President of the American Acne and Rosacea Society. During this event, the Company and Dr. Harper reviewed the 52-week data from license partner Ascletis’ Phase 3 open-label extension clinical trial of denifanstat in moderate to severe acne vulgaris in China and provided an update on Sagimet’s U.S. AURORA Phase 3 clinical trial of denifanstat for the treatment of moderate to severe acne (here).

Publications and Presentations

- **EADV 2026:** In September 2026, Sagimet announced positive full 52-week results from Ascletis' Phase 3 open-label extension clinical trial of denifanstat in moderate to severe acne, which were presented by Ascletis at the European Academy of Dermatology and Venereology (EADV) Congress. Denifanstat showed progressive and sustained improvements across all efficacy endpoints in the open-label extension, including Investigator's Global Assessment (IGA) success with a response rate of 57%, 72% reduction in total lesions, and 77% reduction in inflammatory lesions, and was generally well-tolerated, with no adverse event-related permanent discontinuations (here).

- **Fall Clinical Dermatology 2026:** In October 2026, Sagimet presented the positive 52-week results from Ascletis' Phase 3 open-label extension trial, previously presented by Ascletis at EADV 2026, together with mechanistic data supporting denifanstat's differentiated approach to targeting key aspects of acne pathogenesis: sebum production and inflammation

(here).

Anticipated Upcoming Milestones

- **Denifanstat:** Continue enrollment in the U.S. AURORA Phase 3 clinical trial in moderate to severe acne, with topline data expected in the second half of 2027.
- **TVB-3567:** Initiate a Phase 2 trial in moderate to severe acne by year-end 2026.
- **Topical FASN inhibitor:** Continue development of a topical formulation of a FASN inhibitor for the potential treatment of acne.

Financial Results for the Three and Nine Months Ended September 30, 2026

- **Cash, cash equivalents and marketable securities** as of September 30, 2026, were $275.8 million, which included $27.5 million of investor funds received prior to the closing of the October 2026 underwritten offering of Series A common stock and pre-funded warrants. Pro forma cash, cash equivalents and marketable securities as of September 30 of $355.8 million, includes $80.0 million in additional net proceeds received on October 1 from the October 2026 underwritten offering.
- **Research and development expense** for the three and nine months ended September 30, 2026, was $16.3 million and $34.9 million, respectively, compared to $9.7 million and $32.3 million for the three and nine months ended September 30, 2025, respectively.
- **General and administrative expense** for the three and nine months ended September 30, 2026, was $5.2 million and $14.2 million, respectively, compared to $4.6 million and $13.8 million for the three and nine months ended September 30, 2025, respectively.
- **Net loss** for the three and nine months ended September 30, 2026, was $19.1 million and $43.8 million, respectively, compared to $12.9 million and $41.5 million for the three and nine months ended September 30, 2025, respectively.

About the AURORA Phase 3 Clinical Trial

AURORA (NCT07863193) is a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial of denifanstat in moderate to severe acne. AURORA is anticipated to enroll approximately 800 U.S. patients aged 12 years and older, of which 450 are expected to be adolescents aged 12 to 17 years. Patients will be randomized 2:1 to receive denifanstat 50 mg or placebo once daily for 12 weeks. The trial will have three co-primary endpoints that will be assessed at week 12: the proportion of patients achieving treatment success in a global assessment score, defined as at least a 2-point reduction from baseline with a score of 0 (clear) or 1 (almost clear); absolute change in inflammatory skin lesion counts from baseline; and absolute change in non-inflammatory skin lesion counts from baseline. A subset of approximately 530 patients completing the double-blind period will be eligible to enter a 40-week open-label extension evaluating the long-term safety of denifanstat.

About Denifanstat

Denifanstat is an oral, once-daily FASN inhibitor in development for the treatment of moderate to severe acne. In trials conducted by Sagimet's license partner, Ascletis BioScience Co. Ltd. (Ascletis) in China, denifanstat met all primary and secondary endpoints in a 12-week randomized, double-blind Phase 3 clinical trial in moderate to severe acne vulgaris and was generally well-tolerated and showed improvements in all efficacy endpoints measured at 52 weeks (secondary endpoints of the trial) in an open-label extension clinical trial evaluating denifanstat's long-term safety. Denifanstat is being developed by Ascletis as ASC40 for acne in China and by Sagimet in the rest of world.

About Acne

Acne is one of the most common skin conditions in the U.S., with approximately 50 million Americans affected annually and more than 6.8 million seeking medical treatment for acne each year. Acne affects around 85% of persons between the ages of 12 and 24. Moderate to severe acne accounts for 20% of acne sufferers, or approximately 10 million people in the U.S. annually. There is no cure for acne, and due to its pathology, most patients require chronic management and multiple annual courses of treatment for flare control.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company advancing a portfolio of novel fatty acid synthase (FASN) inhibitors. FASN is a key regulator of the *de novo* lipogenesis pathway, which is overactive in acne and can cause elevated sebum and inflammation. FASN is also implicated in other diseases, including MASH and certain FASN-dependent tumor types. Denifanstat, Sagimet's lead drug candidate, is an oral, once-daily FASN inhibitor currently being evaluated in a U.S. Phase 3 registrational clinical trial for moderate to severe acne. For more information, visit www.sagimet.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding the expected timing of the presentation of data from ongoing clinical trials, Sagimet's clinical development plans and related timelines and anticipated development milestones, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause Sagimet's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this press release are only predictions. Sagimet has based these forward-

looking statements largely on its current expectations and projections about future events and financial trends that Sagimet believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Sagimet's control, including, among others: the clinical development and therapeutic potential of denifanstat, TVB-3567 or any other drug candidates or combination therapies developed by Sagimet; Sagimet's ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines; Sagimet's relationship with Ascletis, and the success of its development and registration efforts for denifanstat; the accuracy of Sagimet's estimates regarding its capital requirements and Sagimet's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Sagimet's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Sagimet operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Sagimet may face. Except as required by applicable law, Sagimet does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except for share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 16,340	$ 9,730	$ 34,870	$ 32,320
General and administrative	5,227	4,604	14,228	13,804
Total operating expenses	21,567	14,334	49,098	46,124
Loss from operations	(21,567)	(14,334)	(49,098)	(46,124)
Total other income	2,418	1,426	5,346	4,654
Net loss	$ (19,149)	$ (12,908)	$ (43,752)	$ (41,470)
Net loss per share, basic and diluted	$ (0.31)	$ (0.40)	$ (0.88)	$ (1.28)
Weighted-average shares outstanding, basic and diluted	62,339,331	32,464,893	49,446,941	32,286,188
Net loss	$ (19,149)	$ (12,908)	$ (43,752)	$ (41,470)
Other comprehensive (loss) income:				
Net unrealized (loss) gain on marketable securities	(483)	41	(680)	(113)
Total comprehensive loss	$ (19,632)	$ (12,867)	$ (44,432)	$ (41,583)

SAGIMET BIOSCIENCES INC.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands)

	As of	
	September 30, 2026	December 31, 2025
Cash, cash equivalents and marketable securities	$ 275,822	$ 113,124
Total assets	$ 282,093	$ 116,482
Current liabilities	$ 37,985	$ 5,101
Noncurrent liabilities	$ 1,927	$ -
Stockholders' equity	$ 242,181	$ 111,381
Liabilities and stockholders' equity	$ 282,093	$ 116,482



Source: Sagimet Biosciences Inc.